



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-4952]

Food and Drug Administration Safety and Innovation Act 907 Public Meeting: Progress on Enhancing the Collection, Analysis, and Availability of Demographic Subgroup Data; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Office of Minority Health (OMH), Office of Women's Health (OWH), the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) are announcing a public meeting seeking feedback and recommendations from patient groups, consumer groups, regulated industry, academia, and other interested parties on FDA's progress in implementing the "Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data," required under the Food and Drug Administration Safety and Innovation Act (FDASIA).

DATES: The public meeting will be held on February 29, 2016, from 9 a.m. to 4 p.m. The deadline for submitting comments regarding this meeting is April 29, 2016.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (B & C), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security

information, please refer to:

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-N-4952 for "FDASIA 907 Public Meeting: Progress on Enhancing the Collection, Analysis, and Availability of Demographic Subgroup Data; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be

made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FDA will post the full agenda approximately 5 days before the meeting at:

<http://www.fda.gov/ForHealthProfessionals/LearningActivities/ucm470074.htm>.

FOR FURTHER INFORMATION CONTACT: Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, email: FDASIA907@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed FDASIA (Pub. L. 112-144) into law. Section 907 of FDASIA directed FDA to publish and provide to Congress a report "addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups, including sex, age, race, and ethnicity, is included in applications submitted to the Food and Drug Administration." Section 907 of FDASIA also directed that 1

year after the publication of the report FDA publish and provide to Congress an action plan outlining "recommendations for improving the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling; on the inclusion of such data, or the lack of availability of such data, in labeling; and on improving the public availability of such data to patients, healthcare providers, and researchers" and to indicate the applicability of these recommendations to the types of medical products addressed in section 907. To fulfill these directives, an FDA-wide steering committee with representatives from CBER, CDER, CDRH, and the Office of the Commissioner (OC) conducted a detailed assessment of the 72 new drug, biologic, and medical device applications the Agency approved in 2011. In August 2013, FDA issued a report on the group's findings entitled "Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products." In August 2014, FDA followed up with a report entitled "FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data," which contained 27 action items divided up into three overriding priorities: data quality, subgroup participation, and data transparency.

The purpose of the public meeting is to report on FDA's progress implementing the Action Plan, to discuss how stakeholders have been affected by these changes, and to solicit feedback and recommendations for further implementation from interested parties and stakeholders.

Some questions we would like the public to comment on during the meeting include:

1. What approaches have been successful in addressing key barriers to recruiting diverse clinical trial populations?

2. What are your key limitations to conducting meaningful data analysis of underrepresented groups?
3. What have you learned about best practices for recruiting a broad representation of subjects for clinical trials? Which practices have been successful and why? Which have not and why?
4. What communication strategies have you successfully used that were also sensitive to the needs of underrepresented populations?
5. What are potential methods FDA should consider using to effectively communicate meaningful information on demographic analyses to a diverse public?
6. What are some of the actual or potential unintended consequences of data transparency you have encountered related to reporting demographic subgroup analysis?

Stakeholders are invited to provide brief comments on these topics during the public comment portion of the meeting, but are not limited to discussing only the previous topics. Since the day-long meeting may not provide enough time to fully address all of these issues, we encourage interested groups to submit longer explanations and comments to the docket.

II. Registration and Request for Oral Presentations

FDA will try to accommodate all participant requests to speak; however, the duration of comments may be limited by time constraints. Those wishing to make oral presentations will be asked to send a brief summary of their comments and registration information (including name, title, firm name, address, telephone, email address, and fax number), and should register by February 1, 2016, by emailing FDASIA907@fda.hhs.gov.

All other participants are asked to register online at:
<http://www.fda.gov/ForHealthProfessionals/LearningActivities/ucm470074.htm> by February 13,

2016, whether they plan to attend in person or listen to the meeting on a live Webcast.

Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the meeting will be based on space availability. Information on how to access the Webcast will be posted approximately 5 days before the meeting at:

<http://www.fda.gov/ForHealthProfessionals/LearningActivities/ucm470074.htm>.

If you need special accommodations due to a disability, please contact FDASIA907@fda.hhs.gov at least 7 days in advance. Persons attending the public meeting are advised that FDA is not responsible for providing access to electrical outlets.

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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